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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,193	12/02/1999	SHIGENORI OHKAWA	2470US0P	9630

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EXAMINER	
ROBINSON, BINTA M	
ART UNIT	**PAPER NUMBER**
1625	13

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/445,193	OHKAWA ET AL.	
	Examiner	Art Unit	
	Binta M. Robinson	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-15,22-26 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-15,22-26 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09445193* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

D tailed Action

The examiner realizes that claim 23 was not addressed at paper no. 13. and that it was erroneously stated at paper no. 13, that claims 1-3, 5-15, and 22 are rejected under 35 U. S. C. 112, first paragraph, for reasons of record at paper no. 8. For this reason, a restart of the time period is granted and the finality of the rejection at paper no. 13 is withdrawn.

Upon review of applicant's amendment at paper no. 12, the 112, 1st paragraph rejection of claims 1-3, 5-15, and 22 for lack of description of the new subgenus is withdrawn and the 112, first paragraph rejection of claims 22, 25, 27, and 29 for lack of enablement for the method of treating all diseases related to neurodegeneration are withdrawn.

(Old rejection)

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-15, and 22 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record at paper no. 10 because the specification, does not reasonably provide enablement for Y being other than O, R4 being other than the moieties claimed on pages 103-105, and R3 being other than phenyl substituted with a dimethyl group. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The applicant does not provide

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).
In terms of the first Wands factor of breadth, Y can be S as well as O, R4 can be an aliphatic hydrocarbon group substituted with aromatic groups other than those depicted on pages 103-105, and R3 can aromatic groups other than the substituted phenyl rings depicted on pages 103-105; in terms of breadth an array of unrelated diseases ranging from Alzheimer's disease to Huntingon's chorea are claimed. In terms of the nature of the invention, which is the second Wands factor, these compounds are used as agents for suppressing neurodegeneration. In terms of the fifth Wands factor, Cell-protecting activity ranges from 30.7 % to 47 %. There are significant differences in cell protecting activity for small changes in structure. For example, compounds 1 and 25 on pages 103 and 104, differ at the e moiety. For compound 1, e is benzyloxy; for

compound 25, the e moiety is benzylmethoxy. However, the cell protecting activity for compound 1 is 30.7 % and for compound 25 is 47%. The level of predictability regarding cell protecting activity is low. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant only tests 7 compounds with very limited markush groupings, whereas Y, R4, and R3 encompass broader Markush groupings. The applicant has only tested Y equal to oxygen, R3 equal to substituted phenyl, and R4 equal to the groups depicted on pages 103-105. These working examples do not encompass the entire scope of Y, R3, and R4. Additionally, these various compounds have not been tested for their affects on the various diseases claimed in claim 28. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

(new rejection)

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 and 26-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for Ya being other than O, R4a being other than the moieties claimed on pages 103-105, and R3a being other than phenyl substituted with a dimethyl group and for the method of treating all of the various diseases, many of which are unrelated. Alzheimer's Disease, which is mediated by serotonin, dopamine, and choline is unrelated to Parkinson's disease, which is a disease where the tremorine compound is diminished. There is currently no known treatment for amyotrophic lateral sclerosis. If Huntington's chorea is not detected in the fetal stage, it can't be treated. There is insufficient data in the specification showing how Huntington's chorea can be treated when this disease is often undetectable until the mid-30s, if not caught in the fetal stages. It is known that blood flow to tissues in diabetic neuropathy is impeded. The specification does not address how pharmaceutical treatments of diabetic neuropathy can be effective in light of the fact that blood flow to tissues is impeded. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The applicant does not provide

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the

level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the first Wands factor of breadth, Y can be S as well as O, R4 can be an aliphatic hydrocarbon group substituted with aromatic groups other than those claimed on pages 103-105, and R3 can aromatic groups claimed other than the substituted phenyl rings depicted on pages 1-3-105; in terms of breadth an array of unrelated diseases ranging from Alzheimer's disease to Huntingon's chorea are claimed. In terms of the nature of the invention, which is the second Wands factor, these compounds are used as agents for suppressing neurodegeneration. In terms of the fifth Wands factor, cell protecting activity ranges from 30.7 % to 47 %. There are significant differences in cell protecting activity for small changes in structure. For example, compounds 1 and 25 on pages 103 and 104, differ at the e moiety. For compound 1, e is benzyloxy; for compound 25, the e moiety is benzylmethoxy. However, the cell protecting activity for compound 1 is 30.7 % and for compound 25 is 47%. The level of predictability regarding cell protecting activity is low. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant only tests 7 compounds with very limited markush groupings, whereas Y, R4, and R3 encompass broader Markush groupings. The applicant has only tested Y equal to oxygen, R3 equal to substituted phenyl, and R4 equal to the groups depicted on pages 103-105. These working examples do not encompass the entire scope of Y, R3, and R4.

Additionally, these various compounds have not been tested for their affects on the various diseases claimed in claim 28. Additionally, the applicant does not test the effect of these compounds on the specific diseases claimed. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-3, 5-15, 22-26, 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 5, page 2 of the amendment at paper no. 12/d, and all other occurrences in claims 2-3, 5-15, 22-26, and 28, the phrase "maybe" are indefinite. The term "wherein" is suggested.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers

for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson

November 3, 2001

Alan L. Rotman

ALAN L. ROTMAN
PRIMARY EXAMINER